REMARKS

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

In the Office Action under reply, claims 1-54 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled. Applicants respectfully traverse this rejection.

In the Office Action of March 12, 2003, the Examiner rejected the claims of the instant application on the grounds that they are not enabled under 35 U.S.C. § 112, first paragraph. More specifically, asserting that the Hutchinson and Matthews references (which were two of 44 references submitted by the applicants in the Information Disclosure Statement filed with the instant application) represent the state of the art, the Examiner concluded that because these two references suggest that testosterone therapy may not have a place in the treatment of female sexual disorders, the present invention is not enabled.

In the response filed on August 8, 2003, applicants provided the Examiner with well-reasoned legal arguments why the Examiner's enablement rejection is not proper. Specifically, applicants traversed the Examiner's rejection with a rigorous application of each of the *Wands* factors and demonstrated why the Examiner's rejection was not well-founded in law or in fact.

In the Office Action under reply, the Examiner, choosing to ignore the legal arguments presented by applicants and the facts supporting the law, repeated the enablement rejection set forth in the Office Action of March 23, 2004. With the current rejection, the Examiner reiterates that because the Hutchinson and Matthews references provide no evidence that androgenic agents may be useful in enhancing sexual desire and responsiveness in a female individual (which applicants note is the invention) doubt exists that the androgenic agents claimed will enhance sexual desire and responsiveness in a female. In support of this statement, the Examiner cites a thirty-three year old case, *In re Marzocchi*, 169 USPQ 367 (CCPA 1971) ("*Marzocchi*").

As a preliminary matter, applicants note that had androgenic agents been known to be useful for the treatment of female sexual dysfunction or disorders at the time of the invention, applicants would not have gone against what was accepted in the art and pursued the invention of the subject matter disclosed in the instant application. Indeed, there would not have been a reason to do so had the use of androgenic agents for the enhancement of female sexual desire and responsiveness been known prior to the filing date of the instant application. Indeed, the concept of patentee's going against what is well-known in the art is a well-established principle in patent law, but is generally used within the context of obviousness rejections. *See, e.g., Arkie Lures, Inc. v. Gene Larew Tackle, Inc,* 119 F.3d 953, 43 USPQ 2d 1294 (Fed. Cir. 1997) ("The patentee "persisted against the accepted wisdom, and succeeded."); *In re Gurley,* 27 F.3d 1551, 31 USPQ2d 1130 (Fed. Cir. 1994) ("A reference maybe said to teach away when a person of

ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."); *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 230 USPQ 81 (Fed. Cir. 1986), *on rehearing,* 231 USPQ 160 (Fed. Cir. 1986) (That the inventor achieved the claimed invention by doing what those skilled in the art suggested should not be done is a fact strongly probative of nonobviousness.).

Notwithstanding the foregoing, applicants now turn to the substance of the Examiner's enablement rejection.

The Examiner's legal basis for the enablement rejection is the *Marzocchi* case. In *Marzocchi*, two claims were rejected as based on an inadequate disclosure. 169 USPQ at 368. The invention of *Marzocchi* involved a technique for improving the adhesion characteristics between glass fibers and vinyl polymer resins. *Id.* The claims before the court, claims 6 and 12, recited the following aspects of the invention:

> 6. In the combination of glass fibers and a vinyl polymer resin composition present as a coating on the glass fiber surfaces, the improvement which comprises mixing the vinyl polymer resin, prior to coating of the glass fibers, with polyethyleneamine in an amount corresponding to 2-10% by weight of the vinyl polymer resin, and in which the amine compound is monomeric vinyl pyrrolidone.

Claim 12 recited the same concept as claim 6, but defined the invention as "a method of producing glass fibers coated with polyvinyl resin strongly bonded to the glass." *Id.*

In the prosecution of the Marzocchi application, the Examiner held claims 6 and 12 to be non-enabled. On appeal to the Board of Patent Appeals and Interferences ("the Board"), affirmed the Examiner's rejection. In so doing, the Board provided the following rationale for the affirmation:

> The term is obviously generic to a considerable number of compounds varying in the number of ethylene groups, the number of amine groups and the relationship of the polyethylene groups to the amine groups, and accordingly does not provide a reasonable guide for those seeing to improve the adherence of vinyl resins to glass. *Id.* at 369

The Court of Customs and Patent Appeals ("CCPA") ***reversed*** the Board's finding that claims 6 and 12 were not enabled. In reversing the Board, the CCPA noted that the Board's comments "indicate nothing more than concern over the *breadth* of the disputed term." *Id* (emphasis added by the CCPA"). After acknowledging the lack of relevance of the Board's concern, the CCPA, provided the following guidance:

> It has never been contended that appellants, when they included the disputed term in their specification, intended only to indicate a single compound. Accepting, therefore, that the term is a generic one, its recitation must be taken as an assertion by appellants that all of the "considerable number of compounds" which are included within the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics. *The only relevant concern of the Patent Office under these circumstances should be over the* ***truth*** of any such assertion. The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. *Id* (emphasis in plain italics added here, emphasis in bold italics added by the CCPA).

By citing *Marzocchi*, it appears that the Examiner's enablement rejection is premised on the Examiner's belief, through a reading of Hutchinson and Matthews, that there is no "truth" to the applicants' invention. Applicants submit that the Examiner's reliance on Hutchinson and Matthews and the Examiner's resultant skepticism of the present invention that stems therefrom, should not obstruct the patentability of the claimed invention for the reasons that follow.

Regarding the "truth" of the assertions in an application, MPEP § 2164.04 provides some guidance on what the ordinary artisan would view as a "truthful" disclosure with the following:

> A specification disclosure which contains a teaching of the manner and process of making and using and invention in terms which correspond in scope to those used in describing and defining the *subject matter sought to be patented* ***must*** *be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph,* ***unless*** *there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.*
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> ...
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> MPEP § 2164.04, p. 2100-182 (8th ed., Aug. 2001, Rev. Feb. 1, 2003).

At MPEP § 2164.05, the issue of what the ordinary artisan would consider a nonenabling is explained with the following:

> If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered.
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> MPEP § 2164.04, p. 2100-185.

In this same manner, if an Examiner asserts that at the filing date of the application the invention was not possible and the applicants counter this assertion with references that show that several years after the filing date of the application the "impossible" became not only possible but accepted in the art, then it must follow, under those circumstances, that the applicants have an enabling disclosure. Such is the case with the present invention.

In support of enablement of the instant application, applicants direct the Examiner's attention to the abstracts attached to the end of this paper. Each of these abstracts describe references that show that androgen therapy has gained acceptance in the scientific and medical communities for the treatment of female sexual dysfunction and disorders. For example, applicants emphasize the following abstracts for the Examiner's convenience:

> Shifren, MAYO CLIN. PROC. 79(4 Suppl.):S19-24 (Apr. 2004). This reference acknowledges that androgen therapies are presently being used in clinical practice and early clinical trial results suggest that they may be both effective and safe in the treatment of FSD.
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> Ghizzani et al., J. ENDROCRINOL. INVEST. 26(Suppl. 3):137-138 (2003). This reference acknowledges that female androgen insufficiency syndrome was defined in July 2001.
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> Nappi et al., J. ENDROCINOL. INVEST. 26(Suppl. 3):97-101 (2003). This reference reports that recent studies have reconsidered the role of androgens in the treatment of female sexual dysfunctions.
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> Mazer et al., OBSTET. GYNECOL. SURV. 58(7):489-500 (2003). This reference reports that transdermal testosterone patches are being developed for androgen therapy in women.
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> Apperloo et al., J. SEX. MARITAL THER. 29(2):87-102 (discussion 177-179) (Mar.-Apr. 2003). This reference acknowledges that androgen substitution is increasingly being used to enhance sexual desire in women based on the presumption that low androgen levels cause low sexual desire.
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> Anastasiadis et al., CURR. OPIN. UROL. 12(6):503-507 (Nov. 2002). This reference acknowledges that the use of androgens for the treatment of decreased libido in women has gained in popularity despite controversial preliminary results.
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> Braunstein, FERTIL. STERIL. 77(Suppl. 4):S94-99 (Apr. 2002). This reference reports that androgen replacement therapy should be given the same consideration as estrogen replacement therapy.
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> Basaria et al., CLIN. ENDOCRINOL. 57(2):209-214 (Aug. 2002). This reference reports the results of methyltestosterone administration to women on estrogen replacement therapy and concludes that low-does androgens should be administered to post-menopausal women with a history of sexual dysfunction and decreased libido.

Bachmann et al., FERTIL. STERIL. 77(4):660-665 (Apr. 2002). This reference evaluates peer-review literature regarding female androgen deficiency syndrome and acknowledges that androgen replacement therapy is currently available but not yet approved (by the FDA; *see also*, Shifren, *supra*).

Munarriz et al., J. SEX. MARITAL THER. 28 (Suppl. 1):165-173 (2002). This reference reports the use of androgen replacement therapy with dehydroepiandrosterone for the effective treatment of androgen insufficiency and female sexual dysfunction.

The present invention was filed on July 27, 2001, and ultimately claims priority to U.S. Patent Application Serial No. 08/959,057 (abandoned) filed on October 28, 1997. Accordingly, the present invention predates all of the references set forth above. The references cited above clearly show that the state of the art subsequent to the filing date of the present invention ***is*** the applicants' invention. Accordingly, based upon the direction that those skilled in the art of treating female sexual dysfunction and disorders have taken since the filing date of the instant application, applicants submit that the Examiner's reliance on the doubt expressed in Hutchinson and Matthews is misplaced. Applicants should ***not*** be deprived of their presumption of validity merely because two prior art references held a view that applicants chose to ignore at the time of the present invention. Further, applicants should not be deprived of their right to disclose to the world by way of a U.S. patent that they were the leaders in the use of androgen therapy for the enhancement of female sexual responsiveness and desire.

Lastly, in response to the Examiner's assertion that applicants use of the term "androgens" is not enabling as requiring "undue experimentation (Office Action, page 1, last paragraph), applicants again refer the Examiner to the attached abstracts where the term "androgen" is used generally by each of the ordinary artisans authoring the articles. In particular, applicants note that each of the articles refer to the administration of "androgens" in the same manner that the applicants do in the instant application. Because the attached abstracts demonstrate that the ordinary artisan would understand the administration of androgens as they are claimed in the instant application, applicants submit that there is no evidence that the ordinary artisan would not understand the scope of the term "androgen" and that undue experimentation would be necessary to discover the scope of the androgens necessary to practice the claimed invention.

CONCLUSION

Because the claims of the instant application are enabled by the disclosure, applicants respectfully request reconsideration and withdrawal of this rejection. With the resolution of the Examiner's enablement rejection, there are no further outstanding issues for this application that need to be addressed; accordingly, applicants respectfully request passage of this application to allowance.

Should the Examiner have any questions concerning this response, he is welcome to contact the undersigned attorney by telephone at 650-330-4913 or by e-mail at canaan@reedpatent.com.

Respectfully submitted,

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